



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:  
BURNO DONATINI :  
SERAL No. 10/069,803 :  
Filed : October 25, 2001 :  
For : NOVEL ... COMPOSITIONS :

Group : 1652

RECEIVED  
SEP 12 2003  
TECH CENTER 1600/2900

600 Third Avenue  
New York, N.Y. 10016

DECLARATION

Commissioner for Patents  
P.O. BOX 1450  
ALEXANDRIA, VA 22313-1450

Sir :

Bruno DONATINI hereby deposes and says :

*I am a medical doctor (MD) holding such degree from the University of Medicine in Reims (France) after having studying in this University from 1978 to 1985*

*I completed my medical studies in 1987-1989 in performing a supplemental degree called « Foreign Medical Graduate Examination in Medical Sciences » (FMGEMS) and a ECFMG in the said University of Reims.*

*I obtained the diploma of physician in 1988 at Hospital Bichat in Paris.*

*I obtained a degree of MD- PhD in immunology at Institut Pasteur at Paris VII in 1988.*

*I obtained a postgraduation degree in statistics applied to clinical research from University of Paris (Paris VI) in 1990.*

*I have also obtained a postgraduation degree in toxicology and in pharmacology from Hospital Fernand Widal in Paris in 1990.*

*That in 1991, I obtained a PhD in Anatomy, namely having performed studies on anatomy of the pancreas, blood, and lymphatic drainage of bowels and pancreas.*

*I have been DESC (resident) in oncology (Hospital Bichat in Paris), and I have personally performed experimental researches in this field on rabbits in 1991.*

*I have been DESC (resident) in gastro-enterology-hepatology in 1991 at Hospital Bichat in Paris.*

*In 1991, I have been a student at School ISA-HEC which is one of the most famous Management School in France for Business.*

*In 1998, I hold a postgraduation degree in Pharmaceutical Medicine in Basel (Switzerland).*

*In 1998, I also obtained a postgraduation degree in pharmacoeconomics from the University of Paris*

*And in 1999-2001, I have been a student on medical and pharmaceutical law and I obtained such degree from the University of Paris (Paris XI).*

*That accordingly, I am an expert both in the problems relating to anatomy and toxicology and pharmacology.*

That he is the inventor of the above application and that the following tests were conducted under his direction to show the synergism of the claimed composition concerning absorption of beta glucans by the hen's intestine.

### TEST DATA

The test involved determining the amount of  $\beta$ -glucan absorption in the hen's intestine under the following conditions as set forth in the following Table:

	Whole Shiitake	Mycelium only	Mycelium + chitosan
Quantity (weight) orally administered	2 g	2 g	2 g
Quantity in intestine (mg)	80	180	400
Increase of $\beta$ -glucan in intestine (mg)	60	120	225
% Absorption	43%	40%	36%
% Absorption p/r quantity of $\beta$ -glucans	27%	50%	100%
Ratio p/r dry weight	7%	15%	31%

Ratio mycelium/shiitake absorption  $(120/60) = 2$

Ratio mycelium + chitosan/shiitake absorption  $(225/60) = 3.75$

Ratio mycelium + chitosan/mycelium absorption  $(225/120) = 1.9$

Soluble quantity potentially to be absorbed:

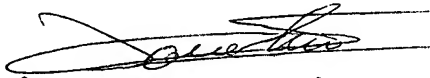
- mycelium + chitosan = 625; ratio p/r: mycelium + chitosan
- mycelium – 300; ratio p/r mycelium + chitosan = 2.1
- shiitake – 140; ratio p/r mycelium + chitosan = 4.5

### CONCLUSION

The presence of chitosan increases the  $\beta$ -glucan absorption from 200 to 210% for the mycelium and from 375 to 450% for the whole shiitake mushroom. This means that chitosan has the property to fix certain proteins and therapeutic substances in an acid environment such as the stomach, and to release these substances in an alkaline environment such as the duodenum and at the same time, keeps the heavy metals chelated. These properties have not been disclosed in the prior art and was unexpected.

The undersigned declares further that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the U.S. Code and that such willful false statements may jeopardize the validity of the above-identified application or any patent issuing thereon.

Date: August 14<sup>th</sup> 2003

  
Bruno DONATINI  
BRUNO DONATINI